ARCHANA NARASANNA, MS, PMP, CCRP

Phone: (650) 741-5671 or (615) 275-9674
Email - narasanna@gmail.com

PROFILE

- Expertise in the following therapeutic research areas – Oncology, Ophthalmology, Cardiovascular Transplant
- Progressive scientific and clinical operational research experience in academia, CRO, and pharmaceutical settings covering pre-clinical studies, healthy volunteer and patient Phase I-III trials, observational, clinical pharmacology, and trials utilizing molecular screening techniques
- Research and development - assisted in a collaborative industrial project-vaccine production, define cell signaling pathway for two lead compounds. Gene mutation detection assay for oncogenes like ErbB2 and PI3KCA on dHPLC Transgenomic WAVE system at Vanderbilt Medical Center,
- Clinical, operational implementation of an assigned protocol, data collection, management of external vendors, and issue resolution
- Experience in directing training, managing budgets, and personnel management.

EXPERIENCE

ICON Clinical Research — February 2022 – Present

Clinical Trial Manager

CTM is responsible for the regional/global coordination of clinical trial management activities *(country & site feasibility, site selection, trial set-up, study execution, trial closure and vendor set up activities)* to meet contract timelines and milestones for internal and/or outsourced trials. Along with management of site facing global vendors activities such as IVRS, Central Lab, ePRO, Imaging, Translation, Printing, Ancillary supplies and Meeting Planners.

Study Assignments –US Sites – Phase I
Oncology –Solid Tumors and Hematological Malignancies

- A Phase I Study to Evaluate the Safety and Pharmacokinetics of a Immunotherapy against cancer with chimeric antigen receptor –T (CART-T) and CD3-bispecific antibodies.(Sites: US and Japan)
  As, US CTM - contributed to the Study–Start-Up, PSV- checklist, slides and budget preparation.

- A Phase I Study to Evaluate the safety, efficacy and clinical activity of CD73 in combination with programmed cell death -1 inhibitor along with standard chemotherapy in advanced and metastatic pancreatic cancer.
  Lead sites and CRAs to address EDC, Lab, and Imaging backlog along with protocol amendment implementation and cohort management.

- A Phase I study to evaluate safety, tolerability and antitumor activity of anti-CD46 antibody-drug conjugate in patients with castration-resistant prostate cancer (MCRPC).
  Manage and supervise CRAs site management and transfer of Clinical Research and Site Management to external CRO.

General CTM activities:

- Provides study leadership and effectively collaborates with study start up, regulatory and finance departments along with other functional leads to meet study timelines and corporate goals.
- Lead study management team meetings via teleconferences with Clinical Research Associates (CRAs), study vendors and training sessions for field CRAs.
- Prepares and presents during monthly Investigator Meetings.
- Proactively identifies and communicates study-related issues (SDV, lab and imaging backlog) and facilitate discussion of potential solutions that can be implemented by the team.
- Coordinate & manage Risk Mitigation Strategies for the study along with project manager.
- Track project deliverables and progress using appropriate CTMS tools.

CareDx **September 2021 – February 2022**

Sr. Clinical Research Associate

Senior Clinical Research Associate (CRA) performs and coordinates all aspects of the clinical monitoring and site management process in accordance with ICH Good Clinical Practices.

- Lead study manager for A multicenter, prospective, observational registry designed to evaluate outcomes of patients receiving HeartCare surveillance (SHORE) and Randomized controlled study Heart Care Immuno-optimization in Cardiac Allografts (MOSAIC).
- Support clinical project timelines, contracts, budgets, vendor management, invoicing, accruals, oversight monitoring visits, meeting milestones and deliverables, and internal/external communications.
- Ensure the study personnel who will conduct the protocol have received necessary updated study materials and instructions; comply with the Study Monitoring Plan, applicable local regulations, ICH/GCP guidelines and IRB approvals.
- Monitor study progress to assure compliance with protocol requirements; coordinate with data management, in house review of electronic CRF data. Work with sites to resolve data queries.
- Coordinate data for development of abstracts, presentations and manuscripts.
- Develop ICF and protocol for the MOSAIC Study.

Genentech **February 2020 – September 2021**
A member of Roche Group

Country Study Manager –USA
Country Study Managers (CSMs) is responsible for providing project coordination and operational solutions of clinical trial to local study teams to enable effective high-quality trial management.

- Coordinate with the global study team to support the day-to-day activities of the phase III and I Breast Cancer and Opthamology studies, including monitoring reports review, problem-solving, issue escalation, timely closure of non- productive sites.
- Primary point of contact for Contract Research Organization (CRO), Clinical Research Associates (CRA) for investigational study site monitoring and management.
- Review and manage country-level Trial Master File (TMF) for quality.
- Update and maintain trial management tracking tools, operational templates, and database.
- Responsible for the oversight and effective coordination of study related supplies (sample collection Kits, IMP, etc.)
- Liaise with clinical sciences as required to clarify and resolve protocol and other study-related questions.
- Prepare and conduct as required country specific investigator and study team meetings.
- Coordinate and manage country-level communications along with reviewing of budget and processing of site invoices.

University of Florida Health Cancer Center **February 2018 – December 2019**

IIT Protocol Development and Project Management

Clinical knowledge and expertise in the protocol development process to support clinical investigators with clinical trials design and implementation of the clinical study. Project management of investigator-initiated trials; including oversight of clinical data.

- Design, develop and write oncology Phase I,II and III investigator-initiated protocols.
- Draft and submit pre-IND, IND initial study packet, amendments, and annual updates to the FDA.
- Responsible for timely registration and periodic maintenance of IIT trials in Clinicaltrials.gov.
- Manage study budgets; by reviewing research study and applicable research-related documents to ensure appropriate resources allocation and adherence to all applicable regulations and institutional standards.
- Coordinate the design, format, and content of CRFs, study reference guides, and forms, including other project-specific documents essential for appropriate implementation of clinical investigations along with data monitoring and validation.

- Work with investigators to ensure optimal compliance and performance to the protocol, regulatory requirements, discrepancy reporting, and ethical practice.

- Work with the Research Managers to improve and solve protocol issues with staff as necessary; review the eligibility of potential patients for enrollment on trials.

- Organize and manage internal team meetings and other trial-specific meetings.

- Stay current with relevant medical literature; attends cross-functional meetings (IRB, SRMC, DISC) as needed to represent clinical operations and study-specific issues.

Flatiron Health **December 2017- March 2020**

Oncology Abstractor: Part-Time / Flexible Hours
Abstraction at Flatiron designed to answer specific scientific questions, reporting on real-world data using project-specific policy and guidelines

- Abstract Oncology data from electronic medical records using Flatiron's proprietary software system.

North East Florida Health Start Coalition **July 2017 – January 2018**

Voluntary Position (Remote)
The Healthy Start Coalition leads a cooperative community effort to reduce infant mortality and improve the health of children, childbearing women, and their families in Northeast Florida

- Responsible for developing Volunteer Handbook, writing and submitting donation/grant applications to secure supplies and funds for ancillary projects to engage participants in coalition programs effectively.

Novartis Pharmaceuticals Corporation **March 2016 – March 2017**

Biosample Clinical Manager (contract through Vivos Professional Services)
Accountable for the operational implementation of the clinical study strategy related to biosamples, including pre-selection, pharmacodynamics, predictive, safety markers, and PK samples, in collaboration with line function (LF) representatives. Accountable for the timely operational execution of these assessments in Oncology protocols, in compliance with Novartis processes and regulatory requirements.

- Core member of the Global Oncology clinical trials team on biomarker, PK, PD strategy for cMET inhibitor INC280 (A2103, A2105 A2108), BCR-ABL inhibitor ABL001 (A2104, A2301), and ALK inhibitor LDK378 (A2112, A2205, and X2103).

- Authored biomarker portions of study-related documents such as protocol, Informed Consent Forms (ICF), case report forms (CRFs), laboratory manual(s), and reviewing data review plans (DRP), reporting and analysis plans (RAP), data handling plans (DHP), data transfer specifications (DTS), Investigator brochures and clinical study reports, etc.

- Managed biomarker samples from collection to analysis, assisting with the relevant data management components, as well as providing input and solutions on the ethical considerations for biomarker aspects of the protocols and informed consents. Primary contact between analytical labs and clinical trial team for coordination, tracking, and analysis of collected samples.

- Prepared and presented training slides for clinical sites and CRAs, across different countries, on samples collection procedures and vendor requirements.

- Involved in preparing study-specific work order, review agreement and contract for vendors and CROs, and design of sample collection kits and logistics for the Trials. Forecast biosample operational costs and review invoice.

- Partnered with KOL, Precision Medicine leader (PML), study biostatisticians, and labs to establish biomarker analysis plan.

- Liaised with outsourcing manager and the CTT to determine analysis labs for biomarkers and other clinical biosamples.

- Provided scientific input on IRB questions related to sample collection, storage, and use to the country representative.

Cancer Genetics Inc. **May 2015 – February 2016**

Senior Clinical Trial Associate

Accountable for ensuring quality deliverables on time and within the scope of the contract, including planning clinical trial study activities, developing project plans, reporting progress, maintaining inventory systems, tracking /monitoring samples, and managing data for clinical studies.

- Maintained oversight of all sponsor-directed study biosample operational activities, regularly reported on the status, and work to fulfill specific requests for personalized medicine initiative for 17 clinical trials.

- Supervised, instructed, and coordinated work of logistics and accessioning team to ensure compliance with all relevant health and safety guidelines, organized and delegated duties of data entry personnel to improve efficiency.

- Initiated, planned, executed, and monitored PD-L1 CDx development for phase III global trial and digital pathology initiative for CRO.

- Prepared study-related analytical plan, kick-off, and investigator meeting slides for biomarker related information; ensuring biomarker decisions communicated, documented, and archived.

- Worked closely with the Clinical Trial Leads/ Managers, CRO partners, Site Monitors, Data Management, Biomarker Scientist, etc. to ensure the study protocol and overall program deliverables are met.

- Coordinated with QA, QC, and operations support on various technical documents.

Vanderbilt University Medical Center, Nashville, TN February 2004 – May 2015

Research Flex Collector, Pediatric Clinical and Translational Research Feb. 2013 – May 2015
Accountable for collection of data from research study participants (parent-child dyad who live in Davidson County, Nashville) in a community and home setting on behalf of the Growing Right On to Wellness (GROW), NHLBI-funded pediatric obesity prevention project.

- Led group of 3 to 5 data collectors at scheduled data collection at community centers from participants to obtain body mass index, conduct survey interviews in addition to anthropometric measurements, genetics, accelerometry, and administer dietary recalls using NDS-R software.

- Recruited and screened participants and obtained informed consent from parents.

Sarah Cannon Research Institute February 2013 – April 2015

Clinical Trial Manager Oncology Phase II/III June 2013 – April 2015
As the study manager for hematological and lung cancer clinical Trials, accountable for planning, executing, and monitoring completion of complex Phase I-IV assigned clinical research protocols on behalf of SCRI. They have included abstracting, assembling, and organizing research data while monitoring adherence to the clinical protocol and preparing reports on the data, working closely with the principal physician investigator, data operations manager, clinical trial sponsor, and study team.

- Made study level operational decisions with minimal oversight and provided input on decisions involving complex and strategic study-related issues.

- Instructed and managed duties of 3 data coordinators to meet study timelines.

- Served as liaison between the principal investigator, site staff, CROs, site monitors, and auditors regarding the study protocol inquiries.

- Ensured tracking and review of protocol deviations and assessed impact on study data and re-educated research staff at weekly study status update call.

Regulatory Document Specialist February 2013 – May 2013
Accountable for processing, tracking, and maintaining regulatory documentation in the SCRI Development and Innovations group while working closely with the regulatory affairs specialists and project teams to ensure compliance while meeting strict deadlines.

- Verified and reconciled PI credentials and other critical regulatory documents file was current and complete for individual sites.

- Built and organized database and tracker for the critical document of investigators and investigative sites of the clinical trial for the regulatory department at SCRI Development and Innovations.

- Reported progress of Trial Master File completeness to department Senior Regulatory Affairs Specialist.

- Archived site/study-specific regulatory documents and correspondence.

Vanderbilt University Medical Center, Nashville, TN

Laboratory Manager, Ophthalmology Research, Eye Institute November 2010 – December 2012
Accountable for developing laboratory guidelines, assembling and compiling research data for presentations and publications, preparing and presenting lectures or laboratory exercises to team members (including coordinating guest lecturers), supervising technical staff, technologists, managing laboratory activities, and preparing budgets for approval and monitoring expenditures against planned budget.

- Reduced annual purchasing cost by up to 50% of budget through successful negotiation with Charles River Laboratories, Invitrogen -Thermo Fisher Scientific Corporation. Etc.

- Supervised and managed research team to delegate tasks and coordinate work of members as it relates to laboratory activity.

- Effectively researched biomedical literature wrote and reviewed protocols, procedures, and technical reports; attended quarterly meetings and implemented changes according to the latest guidelines from Vanderbilt Environmental Health and Safety and Division of Animal Care.

- Allocated charges to appropriate cost centers in compliance with funding agencies; cleared invoices in a timely fashion, and maintain accounts up to date.

Research Assistant III, Division of Hematology/Oncology November 2004 – November 2010
Accountable for developing basic molecular and cellular assays, assay development, inventory maintenance, data entry, scientific techniques protocol preparation, and lab administration under minimal supervision for the investigator, ensuring adequate oversight for compliance issues impacting research projects.

- Developed and established new gene mutation detection assay for oncogenes like ErbB2 and PI3KCA on dHPLC Transgenomic WAVE system, contributing to PI3KCA mutation screens for Personalized Cancer Medicine Initiative screening profile for Breast Cancer.

- Research focused on family of oncogenes like receptor tyrosine kinase ErbB2; Epidermal growth factor family of ligands Amphiregulin, TGFα; TACE; Matrix Metalloproteinase;

- Co-authored publications based on the research and presented data at lab meetings and to the Principle Investigator.

Research Assistant II, Department of Neurosurgery February 2004 – November 2004
Accountable for performing, under moderate supervision, set up and conduct of assigned experiments, and continuing research projects following protocols. Recording of data and reporting of standard or variant results.

- Established tumor tissue bank, collected tissue samples from brain tumors and neurosurgery, maintained freezer log, and reported status of the repository to the chair of the neurosurgery department.

- Organized the Molecular Neurosurgical Research laboratory at its inception for a new faculty member and cloned Ca^{+} activated potassium channel for Regulation of Blood-Brain Tumor Barrier Permeability Project.

Nathan Kline Institute of Science, New York March 2002 – January 2004

Research Assistant II, Center for Dementia Research
Accountable for performing a variety of primary and general laboratory research and clerical tasks on behalf of the Alzheimer/Parkinson's research study

- Cloned, expressed, and purified recombinant rat alpha-synuclein; designed and assembled plasmid constructs to generate transgenic mice for Parkinson's disease; maintained experimental mouse lines.

- Compiled and maintained molecular biology reagent repository for the laboratory.

Indian Institute of Science, Bangalore, India July 1998 – March 2002

Senior Research Fellow, Department of Biochemistry
Work on assigned projects and assist the PI, senior researcher, and Ph.D. students in various phases of a research to understand P. pastoris' biology to develop novel therapeutic agents.

- Assisted in a collaborative industrial project to clone, express, and purify synthetic Hepatitis B surface Antigen (HBsAg) and recombinant VP1 (immunodominant epitope) of Foot-and-Mouth Disease Virus serotype O in Pichia pastoris.

- Cloned Phosphoglycerate Kinase promoter upstream of Hepatitis B surface Antigen (HBsAg) in Pichia pastoris.

EDUCATION

1997 **MS** Medical Microbiology Manipal Academy Of Higher Education, India
1993 **BS** Chemistry, Zoology and Microbiology Bangalore University, India

PRESENTATION & PUBLICATION

2022: "Project Management in Oncology Research" published in SOCRA Source Journal Feb 2023.

2021: Research Track: Oncology Research - "Project Management in Oncology"
SOCRA 2021; Virtual 30th Annual Conference, September 24, 2021

2017**:** "Building Blocks for Targeted Therapy": Implementing Biomarker Strategy for a Global Clinical Trial
New York State SOCRA Chapter Spring Program–March 10, 2017

CONTINUING EDUCATION

2020: Project Management Professional Certification – Renewal 2023;
Genentech -Q2 CSS Functional Meeting Facilitator

2018**:** Data Management for Clinical Research {Coursera};
Pfizer, Drug Discovery & Development Workshop (Onc3D);
SOCRA, Annual Conference, September 27-30th, New Orleans.

2017**:** Writing in Sciences {Coursera}

2016**:** SOCRA CCRP Certification;
Clinical Research Project/Program Management Conference

2015**:** Fundamentals of Project Planning and Management {Coursera}

2013**:** Critical Thinking in Global Health {Coursera}

2012**:** Vanderbilt Program in Research Administration Development Level II
Responsible conduct of research, Audits from every angle

2011**:** Vanderbilt Program in Research Administration Development Level I

SKILLS

Pre-clinical Study	Vendor Management	Biosample Operations
Global Clinical Trials	Phase I, II, and III	Observational & Registry Studies
Community Intervention	Healthy Volunteer Studies	Project management
Budgeting and Forecasting	Investigator Meetings	Contract Negotiation
Personnel Training	Electronic Data Capture	Risk Management
Coaching and Mentoring	Scientific Writing	Molecular and Cell Biology
Clinical Databases	Data Monitoring	Sponsored Trials
Audit Readiness	Institutional Review Board	Internal/External Audits
IND Submission	FDA Annual Reports	ClinicalTrial.gov registration
Confidentiality Agreement	Multi-Center Studies	Key Opinion Leader Collaboration
Site Management Report	Trial Master Maintenance	IMP Management

References and List of Publications available upon request